

10091336

510(k) NOTIFICATION SUMMARY

I. GENERAL INFORMATION

MAY - 7 2010

A. Submission Applicant and Correspondent:

Name: Enthermics Medical Systems, Inc.
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Menomonee Falls, Wisconsin 53051-0443
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Contact Person: Emalee G. Murphy
K&L Gates LLP
1601 K Street, NW
Washington, DC 20006
Tel: 202-778-9428
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B. Name of Device Warmer, Thermal, Infusion Fluid

Trade Name: ivNow Modular Fluid Warmer

Common Name: ivNow, Injection / IV & Irrigation Fluid Bag
Warming Module

C. Regulatory Information:

Classification: Unclassified (Pre-Amendment Device)

Product Codes: LGZ

Panel: General Hospital

Performance Standard: No performance standards have been officially
adopted by FDA.

Device Est. Reg. No: 2131400

D. Devices to Which the New Device is Substantially Equivalent:

TEMP 3 Fluid Warming System (K012276)
EC-770I Fluid Warming Cabinet (K993797)

II. DEVICE DESCRIPTION:

Enthermics Medical Systems' ivNow Modular Fluid Warmer is designed to rapidly warm and maintain the temperature of injection / IV and irrigation fluid bags. Open on two sides with no cover or door, the device consists of a warming area module (alcove) in a "C" shape with a heating element that warms and maintains the temperature of the fluid. The basic device may be used as a single module or [pre]assembled in multiple configurations comprised of 1-6 modules with a common power switch and cord, fastened together by a unique rear mounting panel. The device is available in either 120v or 230v.

When an injection / IV or irrigation fluid bag is placed in the warming alcove, an optical sensor signals to the control that the alcove is occupied. The control then engages the heating element which warms the fluid in the bag. The temperature of the heating element and fluid is monitored by two sets of sensors contained within the device. When the desired temperature of the fluid is reached and confirmed, the real time temperature of the fluid is displayed on a panel at the front of the device (the control display). Internally, the heating element and fluid temperatures are monitored, and the heating element is regulated to raise the fluid to the desired temperature but never beyond that temperature. When the fluid reaches the desired temperature, the control displays the set temperature and a green indicator light next to the control display turns on. The control will continue to monitor the temperature of the heating element and fluid, and regulate the heating element to maintain the fluid at its set temperature indefinitely. The length of time that a particular bag has been warming in the alcove is also monitored and displayed (total residence time monitor display). (See Section IX)

III. INDICATIONS FOR USE

The ivNow Modular Fluid Warmer is intended to warm injection / IV and irrigation fluid bags to a predetermined temperature, and once warm, to monitor and control the temperature of the fluid in the bags. (See Section V)

IV. SUMMARY OF TECHNICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES

The Enthermics Medical Systems' ivNow Modular Fluid Warmer is substantially equivalent to the FDA-cleared Medical Solutions' Temp 3 Warming Cabinet (K012276) and to Enthermics Medical Systems, Inc.'s EC-7701 Fluid Warming Cabinet (K993797). (See Section X)

All three devices are intended to safely store, warm and monitor the temperature of injection / IV and irrigation fluid bags prior to use.

All three devices possess electronic control elements that display the real time fluid temperature and that automatically maintain the desired fluid temperature.

The applicant device is similar to the Medical Solutions' Temp 3 Warmer, in that the ivNow Modular Fluid Warmer also includes an electronic control feature that shows the total time each bag has been warming in the device.

All three devices are "stackable" for ease of use. The Medical Solutions' Temp 3 Warming Cabinet (K012276) and Enthermics Medical Systems, Inc.'s EC-770I Fluid Warming Cabinet (K993797) are both closed heating cabinets, whereas the ivNow Modular Fluid Warmer features open heating alcoves.

Although the three devices differ in physical design, these differences do not affect the substantial equivalence of Enthermics Medical Systems' ivNow Modular Fluid Warmer to the predicate devices.

Substantial Equivalence Comparison Chart:

Product Name	ivNow Modular Fluid Warmer	TEMP 3 Warming Cabinet	EC-770I Fluid Warming Cabinet
Manufacturer	Enthermics Medical Systems, Inc.	Medical Solutions, Inc.	Enthermics Medical Systems, Inc.
Product and Regulatory Status	Warmer, Thermal, Fluid Infusion Unclassified (Pre-Amendment) Product Code LGZ	K012276 Warmer, Thermal, Fluid Infusion Unclassified (Pre-Amendment) Product Code LGZ	K993797 Warmer, Thermal, Fluid Infusion Unclassified (Pre-Amendment) Product Code LGZ
Intended Use	The ivNow Modular Fluid Warmer is designed to store, rapidly warm and maintain the temperature of injection / IV and irrigation fluid bags prior to their use. The residence time duration of the fluid in the compartment is also internally measured and displayed.	The TEMP 3 Warming Cabinet is designed to store, rapidly warm and maintain the temperature of IV fluid bags and irrigation solution bags prior to their use. The residence time duration of the medium in the compartment is also internally measured and displayed.	The EC-770I Fluid Warming Cabinet is designed to safely store and warm irrigation fluid or injection fluids in accordance with the recommended warming temperatures and storage times stated in the fluid manufacturers' labeling.
Construction Materials and Design	Anodized Aluminum with an electric heating element and a silicone substrate heating pad	Powder Coat Finished Aluminum with an electric heating element. Closed heating cabinet.	20 gauge stainless steel exterior casing and door. The cabinet is warmed using a low-heat-density

	element. Open heating "alcoves". The exposed exterior panels are constructed of engineering plastics while the rear mounting panel is of corrosion resistance cut and formed steel.		electrothermal cable array. Closed heating cabinet.
Temperature Controls	Setting Range: Ambient to 43°C Factory preset: 40°C (104° F) Thermal Cutout Temperature: 1°C over set point temperature	Setting Range: Ambient to 43°C Factory preset: 40°C (104° F) Thermal Cutout Temperature: 1°C over set point temperature	
Factor	Total residence time monitor display 1°F over set point	Total residence time monitor display 1°F over set point	
Comparable Sizes and Forms	14" wide by 7" high by 7" deep	21.355" high by 17.163" wide by 6.239" deep	40.7" high by 25.2" wide by 34.9" deep
Voltage	120 V or 230 V	120V	120 V or 230 V
Sterility	N/A	N/A	N/A
Biocompatibility Testing	N/A	N/A	N/A.

V. TESTS AND CONCLUSIONS

The ivNow Modular Fluid Warmer has been tested to confirm it is safe and effective for its intended use. Device testing included a Thermal Performance Test, Life Cycle Test and Control Failure Test. (See Section XI)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Enthermics Medical Systems, Incorporated
C/O Mr. Emalee G. Murphy
K & L Gates LLP
1601 K Street, NW
Washington, DC 20006

JAN 10 2017

Re: K091336
Trade/Device Name: ivNOW Modular Fluid Warmer
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: April 26, 2010
Received: April 27, 2010

Dear Mr. Murphy:

This letter corrects our substantially equivalent letter of May 7, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.

Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091336

Device Name: ivNOW Modular Fluid Warmer

Indications For Use: The ivNow Modular Fluid Warmer is intended to warm injection / IV and irrigation fluid bags to a predetermined temperature, and once warm, to monitor and control the temperature of the fluid in the bags.

Prescription Use X
(Part 21 CFR 801 Subpart D)


and/or

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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